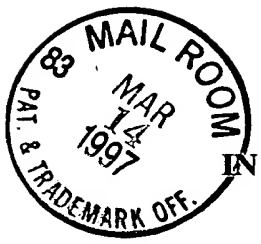

Patent
Attorney's Docket No. 000445-016

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
	)	
Lester P.J. Burton	)	Attn: **BOX PATENT EXTENSION**
	)	
U.S. Patent No. 4,912,155	)	
	)	
Issued: March 27, 1990	)	
	)	
For: ANTIOXIDANT AROMATIC FLUOROPHOSPHITES	)	

DECLARATION UNDER 37 C.F.R. §1.740(a)(17)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Donna M. Meuth, do hereby declare as follows:

I am a patent attorney or agent for the owner of record of the above identified U.S. Patent No. 4,912,155 for which a patent term extension is sought, authorized to practice before the U.S. Patent and Trademark Office, and have general authority from the owner to act on behalf of the owner in patent matters, including the execution of the APPLICATION FOR EXTENSION OF PATENT TERM being submitted pursuant to 37 C.F.R. §1.740.

I have reviewed and understand the contents of the application being submitted herewith.

I believe that the patent is subject to extension pursuant to 37 C.F.R. §1.710.

I believe that an extension of the length claimed is justified under 35 U.S.C. §156 and the applicable regulations.

I believe that the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 C.F.R. §1.720.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
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Date: March 14, 1997

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D. C. 20231

78N5/0613

MR. P.M. PIPPENGER
ETHYL CORP.
451 FLORIDA BLVD.
BATON ROUGE, LA 70801

DATE MAILED
06/18/93

AN 5585
PJH

Pd 6/23/93

MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 10, "status" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 10, "status" below. An explanation of the codes appears on the reverse of the Maintenance Fee Statement. TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.

ITM NBR	PATENT NUMBER	FEE CDE	FEE AMOUNT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT
1	4,912,155	183	930	----	07/020,023	03/27/90	02/27/87	04	NO	PAID

If the "status" column for a patent number listed above does not indicate "PAID" a code or an asterisk (*) will appear in the "status" column. Where an asterisk (*) appears, the codes are set out below by the related item number. An explanation of the codes indicated in the "status" column and as set out below by the related item number appears on the reverse of the maintenance fee statement.

ETHYL CORPORATION
PATENT & TRADEMARK DIV.
JUN 23 1997
RECEIVED

ITM NBR	ATTY DKT NUMBER
1	5585

DIRECT THE RESPONSE TOGETHER WITH ANY QUESTIONS ABOUT THIS NOTICE TO:
COMMISSIONER OF PATENTS AND TRADEMARKS, BOX M. FEE, WASHINGTON, DC 20231

EXHIBIT C

62 FR 2011 printed in FULL format.

FEDERAL REGISTER
Vol. 62, No. 10

Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Public Health Service (PHS)
Food and Drug Administration (FDA)

21 CFR Parts 175 and 178

[Docket No. 91F-0356]

Indirect Food Additives: Adhesives and Components of Coatings; Adjuvants, Production Aids, and Sanitizers

62 FR 2011

DATE: Wednesday, January 15, 1997

ACTION: Final rule.

To view the next page, type .np* TRANSMIT.
To view a specific page, transmit p* and the page number, e.g. p*1

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 2,2'-ethylidenebis(4,6-di- tert -butylphenyl)fluorophosphonite as an antioxidant in adhesives and in the preparation of polymers intended for contact with food. This action responds to a petition filed by Ethyl Corp.

DATES: Effective January 15, 1997; written objections and requests for a hearing by February 14, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3084.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of September 30, 1991 (56 FR 49484), FDA announced that a food additive petition (FAP 1B4281) had been filed on behalf [*2012] of Ethyl Corp., c/o 1150 17th St. NW., Washington, DC 20036. The petition proposed to amend the food additive regulations in § 175.105 Adhesives (21 CFR 175.105) and § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) to provide for the safe use of 2,2'-ethylidenebis(4,6-di- tert -butylphenyl)fluorophosphonite as an antioxidant in adhesives and in the preparation of polymers intended for contact with food.

Subsequent to the filing of the petition, Ethyl Corp. was reorganized to form Albemarle Corp., an independent corporation. As a result of this reorganization, FDA was informed that Albemarle Corp. (c/o Lowell Harmison, Gallery House, 2022 R St. NW., Washington, DC 20009) is now the petitioner of record for this food additive petition.

In FDA's evaluation of the safety of 2,2'-ethylidenebis(4,6-di- tert -butylphenyl)fluorophosphonite (CAS Reg. No. 118337-09-0), the agency reviewed the safety of the additive, including impurities that might be present in the additive. Although the additive itself has not been shown to cause cancer, it may contain minute amounts of methylene chloride, which is a carcinogenic impurity resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as methylene chloride, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the so-called "general safety clause" of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

The food additives anticancer, or Delaney clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive, Scott v. FDA, 728 F.2d 322 (6th Cir. 1984).

II. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned uses of the additive, 2,2'-ethylidenebis(4,6-di- tert -butylphenyl)fluorophosphonite will result in exposure to the additive of no greater than 0.70 parts per million in the daily diet (3 kilograms) which corresponds to an estimated daily intake of no greater than 2.1 milligrams per person per day (mg/person/day) (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological studies. Based on its review of these studies and the low level of exposure to the additive, the agency concludes that there is an adequate margin of safety for the proposed use of the additive.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to

estimate the upper-bound limit of lifetime human risk presented by the carcinogenic chemical, methylene chloride, that may be present as an impurity in the additive. This risk evaluation of methylene chloride has two aspects: (1) Assessment of the worst-case exposure to this impurity from the proposed use of the additive, and (2) extrapolation of the risk observed in the animal bioassays to the condition of worst-case exposure to humans.

A. Methylene Chloride

FDA has estimated the hypothetical worst-case exposure to methylene chloride from the petitioned uses of the additive to be no greater than 0.9 microgram ([mu]g)/person/day (Ref. 3). The agency used data from the National Toxicology Program report (Ref. 4) of an inhalation bioassay on methylene chloride to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the proposed use of the petitioned additive. The results of the bioassay demonstrated that methylene chloride was carcinogenic for mice under the conditions of the study. The test material induced benign and malignant neoplasms in both the liver and lung of both sexes.

The agency also evaluated data from a second study in mice of the same strain as used in the inhalation study. In this study, in which methylene chloride was administered in the drinking water of the mice (Ref. 5), there was no significant increase in the incidence of neoplasms at any site examined. However, assuming that methylene chloride would induce neoplasia at a dose just above the highest level tested in the drinking water study, a maximum potency can be estimated. This estimate is approximately the same as the potency calculated from the data of the inhalation study, providing confidence that using the inhalation study for upper-bound risk assessment is not likely to underestimate any potential risk due to ingested methylene chloride (Ref. 6).

Based on the estimated worst-case exposure of 0.9 [mu]g/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the uses of this additive is 6.6 x 10<-9>, or 6.6 in 1 billion (Ref. 7). Because of numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to methylene chloride is likely to be substantially less than the worse-case exposure, and therefore even the upper-bound limit of lifetime human risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to methylene chloride would result from the proposed use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of methylene chloride present as an impurity in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which methylene chloride may be expected to remain as an impurity, the agency would not expect this impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime human risk from exposure to methylene chloride, even under worst-case assumptions, is very low (less than 7 in 1 billion).

III. Conclusion

FDA has evaluated data in the petition and other relevant material. Based on

this information, the agency concludes that the proposed use of the additive as an antioxidant used in adhesives and in the preparation of polymers intended for contact with food is safe, and that the additive will achieve its intended technical effect. [*2013] Therefore, the agency concludes that the regulations in §§ 175.105 and 178.2010 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 14, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from R. M. Jenkins, Chemistry Review Branch, to D. Harrison, Indirect Additives Branch, dated July 23, 1992.

2. Kokoski, C. J., "Regulatory Food Additive Toxicology," in Chemical Safety

Regulation and Compliance, edited by F. Hombuger, J. K. Marquis, and S. Karger, New York, NY, pp. 24-33, 1985.

3. Memorandum from R. M. Jenkins, Chemistry Review Branch, to D. Harrison, Indirect Additives Branch, dated March 22, 1993.

4. "Toxicology and Carcinogenesis Studies of Dichloromethane (Methylene Chloride) (CAS Reg. No. 75-09-2) in F344/N Rats and B6C3F1 Mice (Inhalation Studies)," NTP Technical Report 306, National Institutes of Health, Publication No. 86-2562, 1986.

5. Memorandum from C. S. Lin, Food Additives Evaluation Branch, to R. Lorentzen, Executive Secretary, Cancer Assessment Committee, dated August 21, 1985.

6. Memorandum from the Quantitative Risk Assessment Committee to W. G. Hamm, Director, Office of Toxicology, dated November 15, 1985.

7. Memorandum from D. N. Harrison, Indirect Additives Branch, to S. H. Henry, Quantitative Risk Assessment Committee, dated November 8, 1993.

List of Subjects

21 CFR Part 175

Adhesives, Food additives, Food packaging.

21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 175 and 178 are amended as follows:

PART 175--INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 175.105 -- Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * * * *	
2,2'-Ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite (CAS Reg. No. 118337-09-0).	For use as an antioxidant and/or stabilizer only.
* * * * * * *	

PART 178--INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

3. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

4. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.2010 -- Antioxidants and/or stabilizers for polymers.

* * * * * [*2014]

Substances	Limitations
* * * * * * *	
2,2'-Ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite (CAS Reg. No. 118337-09-0).	For use only: 1. As provided in § 175.105 of this chapter. 2. In all polymers used in contact with food of types I, II, IV-B, VI-A, VI-B, VII-B, and VIII, under conditions of use B through H described in Tables 1 and 2 of § 176.170(c) of this chapter at levels not to exceed 0.25 percent by weight of polymers. 3. In polypropylene complying with § 177.1520(c) of this chapter, item 1.1, in contact with food of types III, IV-A, V, VII-A, and IX, under: (a) Conditions of use B through H described in Tables 1 and 2 of § 176.170(c) of this chapter at levels not to exceed 0.25 percent by weight of the polymer; or (b) Condition of use A, limited to levels not to exceed 0.1 percent by weight of the polymer; provided that the food-contact surface has an average thickness not exceeding 375 micrometers (0.015 inch). 4. In olefin copolymers complying with § 177.1520(c) of this chapter, items 3.1a or 3.2a, and containing not less than 85 percent by weight of polymer units derived from propylene, in contact with food of types III, IV-A, V, VII-A, and IX, and under: (a) Conditions of use C through G, described in

Tables 1 and 2 of § 176.170(c) of this chapter, limited to levels no greater than 0.2 percent by weight of the copolymers; or
(b) Conditions of use A, B, and H, limited to levels no greater than 0.1 percent by weight of the olefin copolymers; provided that the food-contact surface has an average thickness not exceeding 375 micrometers (0.015 inch).
5. In olefin polymers complying with § 177.1520(c) of this chapter, items 1.2 or 1.3 in contact with food of types III, IV-A, V, VII-A, and IX, under conditions of use A through H, described in Tables 1 and 2 of § 176.170(c) of this chapter at levels not to exceed 0.1 percent by weight of the polymers; provided that the food-contact surface has an average thickness not exceeding 375 micrometers (0.015 inch).
6. In polyethylene complying with § 177.1520(c) of this chapter, items 2.1 or 2.2, having a density of not less than 0.94, in contact with food of types III, IV-A, V, VII-A, and IX, and under:
(a) Conditions of use B through H, described in Tables 1 and 2 of § 176.170(c) of this chapter limited to levels not to exceed 0.2 percent by weight of the polymers; or
(b) Condition of use A, described in Tables 1 and 2 of § 176.170(c) of this chapter, limited to levels not to exceed 0.1 percent by weight of the polymer; provided that the food-contact surface has an average thickness not exceeding 125 micrometers (0.005 inch).
7. In olefin copolymers complying with § 177.1520(c) of this chapter, items 3.1a, 3.1b, 3.2a, or 3.2b, containing not less than 85 percent by weight of polymer units derived from ethylene and having a density of not less than 0.94, in contact with food of types III, IV-A, V, VII-A, and IX, and under:
(a) Conditions of use C through G, described in Tables 1 and 2 of § 176.170(c) of this chapter limited to levels not to exceed 0.2 percent by weight of the copolymers; or
(b) Conditions of use A, B, and H, limited to levels not to exceed 0.1 percent by weight of the copolymers; provided that the food-contact surface has an average thickness not exceeding 125 micrometers (0.005 inch).
8. In olefin polymers complying with § 177.1520(c) of this chapter, items 3.1a, 3.1b, 3.2a, or 3.2b containing not less than 85 percent by weight of polymer units derived from ethylene, in contact with food of types III,

IV-A, V, VII-A, and IX, under conditions of use A through H, as described in Tables 1 and 2 of § 176.170(c) of this chapter at levels not to exceed 0.1 percent by weight of the copolymer; provided that the food-contact surface has an average thickness not exceeding 75 micrometers (0.003 inch).

9. In polyethylene phthalate polymers complying with § 177.1630 of this chapter in contact with food of types III, IV-A, V, VI-C, VII-A, and IX, and under:

(a) Conditions of use B through H, described in Tables 1 and 2 of § 176.170(c) of this chapter, limited to levels not to exceed 0.3 percent by weight of the polymers; or

(b) Condition of use A with food of types III, IV-A, V, VII-A, and IX, and limited to levels not to exceed 0.1 percent by weight of the polymers; provided that the film thickness does not exceed 875 micrometers (0.035 inch).

* * * * * * *

Dated: January 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-1021 Filed 1-14-97; 8:45 am]

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